James B. Gulliford
Assistant Administrator
Office of Prevention, Pesticides and Toxic Substances
U.S. Environmental Protection Agency
Remarks on EPA's Chemical Assessment and Management Program (ChAMP)
at the
Soap and Detergent Association 2008 Fall Meeting
September 24, 2008

I want to thank the Soap and Detergent Association for the invitation to the Agency to speak. EPA Administrator Steve Johnson, had planned to be here today but is now visiting Texas dealing with the wake of Hurricane Ike and the many environmental issues the state now faces. He asked me to express his regrets that he is unable to be here with you.

I'm pleased the soap and detergent, and consumer products industries are working to be leaders in the race to "go green." Over the years, your industry has been responsible for providing products that improve our quality of life, and also embracing green technologies and chemicals. As you well know, consumers are searching for ways to express their environmental preference through their product choices. You provide products that support this interest on their part, and in doing so, put more environmentally sustainable products into the consumer marketplace. We very much appreciate this forward looking activity on your part, and appreciate your willingness to work with us in this regard.

For example, I want to just recognize the effort SDA has made as a participant and advocate for our Design for the Environment product recognition program, or DfE as you may know it. Many of your member companies have invested heavily in safer product formulation and now proudly display the DfE logo. And, the importance of this logo is growing every month.

As I said, consumers want a way to recognize green products and the DfE logo provides that recognition. SDA has also worked closely with EPA on the development of the CleanGredients database, a marketplace for safer cleaning product ingredients that also meet the DfE screens. We all win in this process -- our interest in environmentally friendly products, consumer preference for these products, and your ability to meet this increasingly important market. Again, I appreciate your leadership in this area and look forward to continued collaboration and success.

That said, I'd like to spend my time with you today discussing one of Administrator Johnson's and my highest priorities, our ChAMP program. As I begin, I want to take a moment to thank SDA for their input and support of ChAMP. In particular, we appreciate the fact that a number of you took the opportunity to examine and comment on our early posting of ChAMP 'risk based prioritizations', or participated in our stakeholder meetings as we have sought input on our chemical management and chemical regulation path forward.

As you know, ChAMP encompasses the commitment made by President Bush, Canadian Prime Minister Stephen Harper and Mexican President Felipe Calderon at the August 2007

Security and Prosperity Partnership Summit that committed our three countries to work together to accelerate and strengthen the management of chemicals in North America.

This commitment includes enhanced regulatory cooperation between the U.S. and Canada on high and moderate production volume chemicals, the establishment of a Mexican chemical inventory, coordinated R&D on new approaches to testing and assessment, and the development of mechanisms to share scientific information and best practices. The Administrator and I are confident this collaborative work will lead to stronger, more protective approaches to chemicals management in North America.

Under ChAMP, the U.S., by 2012, will complete prioritization assessments and initiate action, as needed, on 6,750 high and moderate production volume chemicals manufactured or imported in the U.S. each year. This is a daunting task for the Agency to be sure but we plan to build on and integrate our previous work on the HPV Challenge Program, the information gathered in the 2006 Inventory Update Reporting Rule, or IUR, as well as Canada's categorization work.

For the more than 2,200 HPV Challenge program chemicals, we will use the hazard data already collected, along with chemical use and exposure information received in the 2006 IUR update, to develop Risk-Based Prioritizations, or RBPs, as we call them. The RBPs detail our preliminary evaluation of potential risks and identifies additional data or testing that may be needed to better characterize the chemical. This process also enables us to make judgments as to whether control measures should be pursued to address potential exposure risks or whether the chemical is a low priority for further action.

Since we launched ChAMP, we have not been idle. To date, we have posted RBPs for 102 chemicals and are working to complete another 48 chemicals, for a total of 150 chemicals by the end of September. We plan to more than double our output next year. Through this process, EPA is making judgments on whether a chemical presents either a high, medium, or low priority and we are using these judgments to tee them up for further action.

If we conclude that a chemical is a priority for action, and that additional information is needed to clarify our assessment or if regulatory control action may be needed, there are several steps the agency can initiate under TSCA. We can informally request additional information from manufacturers or importers. We can also issue reporting rules under Section 8 of TSCA, Significant New Use Rules and/or test rules. We can also pursue product stewardship approaches or Challenge programs, as well as initiate efforts to identify and consider safer substitutes under the Design for the Environment program.

While our efforts over the coming years will be focused on meeting the ChAMP assessment commitments, we do plan, within current resources, to take action on high and medium priority cases, in a staged, strategic manner. Specifically, we will promptly follow-up on cases where particularly serious issues are identified – these are identified as "high priority special concern" cases. For example, out of the 102 assessments completed so far, we have already begun following up on two "high priority special concern" chemicals to receive additional exposure information to help clarify or resolve the risk issues identified in the RBP.

The manufacturers of the two chemicals have indicated that they are surveying their customers and have already begun providing us with additional exposure and use information. Following receipt of that information, we will determine whether further action is warranted.

For cases identified as high priority, but not "special concern," our goal is to initiate follow-up action by 2012. Most medium priority cases will be dealt with after 2012. Our primary focus will be to complete the ChAMP assessments but when we see the need for action or the need for a better understanding of the chemical, we won't hesitate to use all our available tools to further efforts to protect public health and the environment.

In addressing the almost 4,000 moderate volume chemicals, or MPVs, we will develop hazard based prioritizations, or HBPs – it wouldn't be an EPA program without a whole bunch of new acronyms, right? The MPVs are those chemicals that are produced/imported between 25,000 and one million pounds a year in 2005. Recognizing that we do not have "HPV Challenge" data or IUR use and exposure information for most of the MPV chemicals, our approach relies on existing available test data, structure activity relationship (SAR) analyses, and the results of the Canadian 'categorization work', when available, to prepare the HBPs, which also will identify next steps, where needed. The "next steps" would likely focus initially on obtaining additional exposure information to provide a risk context. In most cases, we expect to defer follow-up action until after 2012, although if the need arises, we will act promptly.

Today, we posted an initial set of HBPs for nine MPV chemicals. An additional 46 will post by the end of this month. Next year, we plan to significantly ramp up the pace for the MPV assessments.

I certainly don't need to tell this group that we recognize this is a significant undertaking. I also don't need to tell this group that we recognize not everyone agrees with our approach, our process, or our commitment to get this done. I do need to tell you that while we recognize that the hurdle is high, we have every reason to believe that we will be successful in achieving this goal and that ChAMP will continue to be a priority for the Agency.

My other purpose in joining you today is to share with you the Administrator's decisions on the ChAMP enhancements that have been under consideration. At the Global Chemical Regulation Conference in Baltimore earlier this year, the Administrator announced two possible program enhancements. First was the possibility of resetting the TSCA inventory and, second, the consideration of a program similar to the HPV Challenge for "inorganic" HPV chemicals. Between March and June, we met with a wide range of individuals, from senior executives to the general public, representing companies, trade associations, NGOs, academia, and State, local, and tribal governments. We held eleven ChAMP-specific stakeholder meetings, including a public meeting in May, and we made 20 ChAMP presentations in the U.S. and abroad during that time. If you were an interested stakeholder, we sought your input and we benefited from what we heard.

The overarching theme of the feedback was an appreciation for the pace of the SPP ChAMP commitments and the importance of setting and meeting milestones to ensure that we meet these goals – we agree. Concerns were raised about underlying data quality and

transparency on our hazard and exposure characterizations and the challenges before us with using IUR Confidential Business Information in the exposure and risk assessments. We understand and are committed to finishing the HPV Challenge work, including needed test rules, and assuring those data sets are complete and accurate. In the context of CBI, we will apply data and science analysis to reach appropriate RBP determinations, but one of the challenges is adequately explaining our reasoning while protecting CBI. This will be an issue for further discussion as we engage further with our stakeholders. Many of you emphasized the importance of leveraging efforts underway in Canada and the European Union to reduce the burden to industry and to us, and again -- we agree.

Another area that received a lot of discussion in the stakeholder process was use of the TSCA risk list. The Administrator and I continue to believe that the risk list is one of the tools that can be used to follow-up on ChAMP priorities and we will continue to seek input on how this option can be used.

Regarding the inventory reset, there was considerable interest in making sure that (1) we have a transparent process, (2) we use a multi-year window for determining the chemicals currently in commerce, and (3) that we maintain the information we currently have on those chemicals no longer in commerce, that will not be on the reset inventory.

Regarding the inorganic HPV Challenge, there was general recognition of the need to deal with these chemicals, however, there were concerns about relying on a voluntary approach, whether the timing was right considering what else the Agency has on its plate, as well as the challenge faced by companies as they work to meet their REACH obligations.

For those of you who may be interested in more specific details on all the feedback, meeting summaries and copies of written comments can be found on the ChAMP website.

Based on the input we received, and following careful consideration of the issues before us, the Administrator asked that I share with you that he has decided to proceed with a reset of the TSCA Inventory. At present, there are more than 83,000 chemicals on the inventory, and we can all attest to the fact that a great many of these are no longer being produced or imported. It is time to make the TSCA Inventory a more valuable tool for the Agency, industry, the environmental community, and the public by updating it to reflect only those chemical substances currently manufactured or imported in the United States, as called for under TSCA section 8(b).

We favor a "clean reset" which would remove chemicals no longer being manufactured or imported. Currently, we envision that this would be achieved by inviting companies to certify that they have manufactured or imported specific chemicals within an appropriate timeframe – for example, a three-year period was used in the creation of the original inventory. We would seek comment on a draft updated TSCA Inventory before completing the reset.

Chemicals that remain on the reset TSCA inventory would maintain their current status. A new chemical notice would only be needed if a company decided, at a later date, to produce a chemical no longer on the reset inventory. We would also anticipate periodic resets in the future to continue to keep the Inventory current.

Again, I believe that everyone agrees that it's time to make the TSCA Inventory a more useful tool and the time is now to begin this effort.

After careful consideration and much discussion, the Administrator has also decided to proceed with a phased Inorganic HPV Challenge approach that will allow us to obtain, review, and evaluate hazard and use information on HPV inorganic chemicals. We will begin with a "development" phase that will allow us to take full advantage of the work completed or underway by the OECD, Canada's categorization efforts, and future REACH work. This phase will also allow further stakeholder engagement and consideration of new approaches based on HPV Challenge experience. We anticipate that the implementation phase would include a sponsorship opportunity but, in the absence of sponsorship or where timely/complete action by the sponsor does not occur, a vigorous use of test rules would be pursued to ensure the submission of quality data sets.

Following a two to three year data development period, we would, after 2012, anticipate beginning a ChAMP-type prioritization assessment of the inorganic HPV chemicals. This assessment would apply the IUR exposure/use reporting on inorganics which will be received in 2011. Subsequent to this work, we would envision the preparation of prioritization assessments on Moderate Production Volume inorganic chemicals which would inform decisions on any needed next steps for these chemicals.

In wrapping up my remarks, let me summarize. We will, by 2012, prepare risk-based prioritizations on organic HPV chemicals and hazard-based prioritizations on MPV chemicals, and initiate needed action, in a timely but staged manner. We will immediately begin the steps necessary to reset the TSCA Inventory. We will, through a phased implementation process, collect data and prepare risk-based prioritizations on inorganic HPV chemicals, which would be followed by steps to address MPV inorganic chemicals. In all of this, in the interest of EPA regulatory authority, industry responsibility, and public interest -- we will apply our energy and the principle of sound science to assure the protection human health and the environment.

Let me also state, that while we have decided to proceed, we intend to continue to engage you and all of our stakeholders on exactly how to proceed. I am hopeful that we will have your full support and the full engagement of all of our stakeholders as we begin the next phase of this very important program.

The Administrator and I believe that the ChAMP program, including the enhancements I announced here today, provides a strong and vigorous approach to assessing and managing existing industrial chemicals and will provide the next Administration with a sound and comprehensive foundation for delivering effective chemical assessment and management in the U.S.

Again, we look forward to continuing to work with all of you on the ChAMP program and thanks for allowing me to join you today!